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Attorney's Docket No.: 08919-016003  
Client's Ref. No.: 13A-870916 (CON)

**U.S. PATENT AND TRADEMARK OFFICE**  
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Applicant : Chen-Kun James Shen      Art Unit : 1636  
Serial No. : 09/977,432      Examiner : Sumesh Kaushal  
Filed : October 15, 2001

Title : HS-40 ENHANCER-CONTAINING VECTOR

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Attached to this facsimile communication cover sheet is **STATEMENT OF  
SUBSTANCE OF INTERVIEW OF FEBRUARY 8, 2005**, faxed this 11<sup>th</sup> day of March,  
2005, to the United States Patent and Trademark Office.

Respectfully submitted,

Jiauming Hao  
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Chen-Kun James Shen                      Art Unit : 1636  
Serial No. : 09/977,432                                      Examiner : Kaushal, Sumesh  
Filed : October 15, 2001  
Title : HS-40 ENHANCER-CONTAINING VECTOR

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**STATEMENT OF SUBSTANCE OF INTERVIEW OF FEBRUARY 8, 2005**

Applicants would like to thank Examiners Remy Yucel and David Guzo for granting the telephone interview on February 8, 2005, regarding this application.

During the interview, Applicants' counsels, Y. Rocky Tsao (Reg. No. 34,058) and Jianming Hao (Reg. No. 54,694) discussed independent claim 33. This claim, rejected for obviousness, is drawn to a retroviral expression vector containing a mutant enhance element (SEQ ID NO: 1). More specifically, Applicants' counsel reiterated unexpected advantages exhibited by the claimed vector, which was previously presented in a declaration by the inventor. A letter sent to Examiner Yucel before the interview summarizes the unexpected advantages and related issues discussed in the interview. A copy of this letter is attached hereto as "Exhibit A".

The Examiners countered that the declaration noted above did not provide details of the retroviral vectors and transgenic method exemplified therein, and therefore declined to consider the declaration. Applicants' counsel proposed submitting a substitute declaration to include the alleged missing details. The Examiners agreed.

**CERTIFICATE OF TRANSMISSION BY FACSIMILE**

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NO. 8140 P. 3

Applicant : Chen-Kun James Shen  
Serial No. : 09/977,432  
Filed : October 15, 2001  
Page : 2 of 2

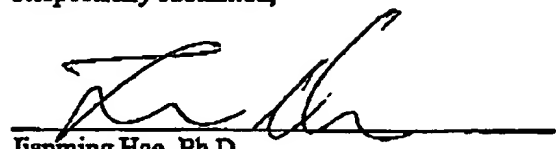
Attorney's Docket No.: 08919-016003 / 13A-870916  
(CON)

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Respectfully submitted,

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3-11-2005

  
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Frederick P. Fish  
1859-1930

W.K. Richardson  
1859-1991

## VIA FACSIMILE

February 8, 2005

Examiner Yucel Irem  
U.S. Patent & Trademark Office  
Commissioner for Patents  
Washington, D.C. 20231

Re: HS-40 ENHANCER-CONTAINING VECTOR  
Appl. No.: 09/977,432  
Our Ref.: 08919-016003

Dear Examiner Irem:

Thank you for granting a telephone interview, scheduled for 2:30 pm, Feb. 8, 2005 to resolve an issue raised in the final office action. As I know you are busy, I will limit this discussion to claim 33. Hopefully, the summary below will facilitate your understanding of this issue.

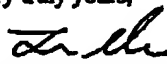
Claim 33, rejected for obviousness, covers a viral expression vector that contains, among others, a mutant element of the HS-40 enhancer, i.e., SEQ ID NO:1 or its complement. In the response to the final office action and two subsequent supplemental responses, we presented unexpected advantages of the claimed vector as compared with that of (1) a vector containing wild type counterpart of SEQ ID NO: 1 ("control vector") or (2) a vector described in a non-prior art reference Lung et al., which contains wild type HS-40 enhancer. The table appended to this letter shows the expression patterns by these three vectors.

In the advisory action dated January 27, 2004, Examiner Kaushal countered that the expression pattern of the claimed vector in transgenic mice is not unexpected as the Lung vector "is capable of providing high level of gene expression in [cancer cell lines]."

According to MPEP 716.02(a), "[e]vidence showing that the claimed [vector] was more effective than the closest prior art [vector in driving expression of a transgene in transgenic mice] was sufficient to overcome the rejection under 35 U.S.C. 103, even though ... the claimed [vector] was an average performer on [driving expression of a gene in cancer cell lines]." Also, note that there was a long felt but unsolved need for a vector having the above-mentioned unexpected advantages. See, e.g., the Specification, the paragraph bridging pages 4 and 5. Indeed, the Lung's failure to solve the problem supports this unexpectedness. The unexpected expression pattern by the claimed vector is sufficient to overcome the obviousness rejection.

We look forward to discussing with you the above issue at the interview.

Very truly yours,

  
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Examiner Yucel Irem

February 8, 2005

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Table. In vivo and in vitro expression patterns by three vectors at issue

	A vector of claim 33	Control vector	Lung vector
In vivo expression pattern of a transgene in mice	1. Developmental stage-independent: Expressed in embryo stage and continued to express in adulthood.  2. Position-independent.	1. Developmental stage-dependent: Expressed in embryo stage but dropped significantly in the adult.  2. Position-dependent.	1. Failed to drive expression of a gene.  2. N/A
In vitro expression in cancer cell lines	Yes.	Yes.	Yes.

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